IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiffs, v. AMGEN, INC. Defendant.	Case No. 18-924-CFC

JOINT MEMORANDUM IN SUPPORT OF THE PARTIES' PROPOSED JURY INSTRUCTIONS

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In accordance with the parties' agreement and as approved by the Court (D.I. 502), Plaintiff Genentech, Inc. and Defendant Amgen, Inc. hereby submit this memorandum in support of the parties' competing proposed jury instructions (D.I. 498, 499).

I. Proposed Instruction 2: The Parties and Their Contentions

I will now review for you the parties to this action, and the positions that you will have to consider in reaching your verdict. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

To refresh your recollection, the parties are Genentech, Inc., the Plaintiff, and Amgen Inc., the Defendant. Genentech is asserting four U.S. patents in this case: (1) U.S. Patent No. 6,627,196 ("the '196 Patent"); (2) U.S. Patent No. 7,371,379 ("the '379 Patent"); (3) U.S. Patent No. 10,160,811 ("the '811 Patent") and (4) U.S. Patent No. 8,574,869 ("the '869 Patent"). I will refer to the '196, '379, and '811 patents collectively as the "Dosing Patents." I will refer to the '869 Patent as the Kao Manufacturing Patent. I will refer to all four patents collectively as the Patents-in-Suit.

Amgen filed a Biologics License Application ("BLA") for a biosimilar of Herceptin, a drug used to treat cancer. Herceptin was first marketed by Genentech in 1998, and its active ingredient is trastuzumab. Amgen began selling its FDA-approved trastuzumab biosimilar product, called Kanjinti, in the U.S by July 18, 2019. ABP 980 is the active ingredient found in Kanjinti.

I will now overview the positions each side has taken. Genentech alleges that Amgen infringed, is currently infringing, and will continue to infringe:

1. claims 11 and 22 of the '196 Dosing Patent;

2. claims 11 and 21 of the '379 Dosing Patent;

3. claims 6 and 7 of the '811 Dosing Patent; and

4. claims 5 and 8 of the Kao Manufacturing Patent.

I will refer to these claims collectively as the Asserted Patent Claims. Additionally, Genentech contends Amgen's infringement of the Asserted Claims is

willful. Genentech seeks damages adequate to compensate for Amgen's infringement.

GENENTECH'S PROPOSAL: Amgen denies that it infringes any of the Asserted Patent Claims. Amgen further asserts that each of the Asserted Patent Claims is invalid. Amgen also denies that it has willfully infringed the Asserted Claims.

AMGEN'S PROPOSAL: Amgen denies Genentech's infringement allegations as to all Asserted Patent Claims. Amgen further asserts that each of the Asserted Patent Claims is invalid because the inventions claimed were not new and were obvious at the time Genentech claims to have invented them. Amgen also contends that the Asserted Claims of the Dosing Patents are invalid for incorrect inventorship and/or derivation. Amgen also contends that the Asserted Claims of the '196 Dosing Patent, the '379 Dosing Patent, and the Kao Manufacturing Patent are invalid because the patents do not sufficiently describe and enable the claimed inventions and the Asserted Patent Claims themselves are indefinite. Amgen further contends the '869 patent is unenforceable for inequitable conduct.

You will be asked to determine the issues of infringement, invalidity, willful infringement, [AMGEN'S PROPOSAL: inequitable conduct,] and damages according to instructions I will give you in a moment.

A. Genentech's Position

Amgen's details regarding invalidity are unnecessary, and derivation and inventorship should be stricken. *See* D.I. 445; 10/16/2019 Hearing Tr. 195:18-208:3.

B. Amgen's Position

Amgen's recitation is comparable to that Genentech provided regarding infringement. Amgen's defenses are timely (D.I. 456). Proposal on inequitable conduct withdrawn.

II. Proposed Instruction 3: Burdens of Proof

> Put differently, if you were to put each party's evidence on the opposite sides of a scale, the evidence supporting the party with the burden of proof would have to make the scales tip [GENENTECH'S PROPOSAL: somewhat on the side] [AMGEN'S PROPOSAL: in favor] of that party.

A. Genentech's Position

Genentech's explanation is what Amgen proposed in *Hospira*. C.A. No. 1:15-cv-839-RGA, D.I. 323 at 12; *see also* AIPLA Model §B ("slightly greater than 50%").

III. Proposed Instruction 4.2: Independent and Dependent Claims

> An "independent" claim sets forth all of the requirements that must be met in order for a process, [GENENTECH'S PROPOSAL: a product made using a process,] of the use of a product according to a method to be covered by that claim, and thus infringe that claim.
>
> A process, [GENENTECH'S PROPOSAL: a product made using a process] or the use of a product according to a method is covered by, and therefore infringes, a dependent claim only if it meets all of the requirements of both the dependent claim and the claim or claims from which the dependent claim depends.

A. Genentech's Position

Genentech's proposal reflects its Kao patent infringement claim under §271(g) (product made by patented process).

B. Amgen's Position

The Asserted Patent Claims do not include product-by-process claims. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006).

IV. Proposed Instruction 5.1: Infringement Generally

GENENTECH'S PROPOSAL: Genentech also alleges that Amgen's filing of its BLA is an act of infringement of all the Asserted Patent Claims.

A. Genentech's Position

Genentech alleges infringement in multiple, independent ways, including under §271(e)(2)(C)(1) by filing a BLA. *See Bayer AG. v. Biovail Corp*., 279 F.3d 1340, 1350 (Fed. Cir. 2002) ("infringement under § 271(e)(2)(A) by submission of an ANDA is not synonymous with infringement under § 271(a) by a commercial product"). "Damages" for such claim "may be awarded," §271(e)(4)(C), and it is properly tried to a jury. *See Sepracor Inc. v. Dey L.P.*, 2010 WL 2802611, at *3 (D. Del. July 15, 2010).

In *Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562 (Fed. Cir. 1997), and *Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023 (Fed. Cir. 2019), the court entered judgment on §271(e) claims where evidence beyond the ANDA/BLA demonstrated non-infringement. Those cases do not suggest that commercialization supplants §271(e).

B. Amgen's Position

"Patentees were given a jurisdictional basis for bringing suit in federal district court under 35 U.S.C. § 271(e)(2) when, in light of Section(s) 271(e)(1), the [biosimilar] applicant was not making, using, or selling the patented product, the traditional statutorily-defined acts of infringement." *Glaxo, Inc. v. Novopharm,*

Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). Courts assess this technical act of infringement by conducting a "hypothetical inquiry": if FDA approves the drug application and the "drug *were* put on the market," "*would* [it] infringe the relevant patent"? *Id.* at 1569–70.

But now that FDA has approved Kanjinti and is "currently marketed, it is unnecessary to determine 'what is likely to be sold,' as is required for a technical act of infringement." *Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023, 1030-31 (Fed. Cir. 2019), *reh'g granted, opinion modified*, 776 F.App'x 707 (Fed. Cir. 2019). Instead, "infringement turns on … conventional principles of patent infringement." *Id.* at 1031.

Genentech's proposal is unnecessary, inefficient, and would confuse the jury.

V. Proposed Instruction 5.2: Direct Infringement

A. Disputed Proposal 1

GENENTECH'S PROPOSAL: Someone can directly infringe a patent without knowledge of the patent or without the knowledge that their actions are infringing the patent. They also may directly infringe a patent even though they believe in good faith that what they are doing does not infringe a patent or if they believe in good faith that the patent is invalid.

AMGEN'S PROPOSAL: Amgen's knowledge of the Kao Manufacturing Patent and Amgen's intent are irrelevant to your determination of infringement of the Kao Manufacturing Patent.

1. Genentech's Position

Genentech clarifies that intent is irrelevant to direct infringement.

B. Disputed Proposal 2

AMGEN'S PROPOSAL: Genentech does not accuse Amgen of direct infringement of the Dosing Patents, but Genentech does accuse Amgen of induced infringement of the Dosing Patents. In order to prove that Amgen induced infringement of the Dosing Patents, Genentech must prove an act of direct infringement of the Dosing Patents by a third party. To prove direct infringement of the Dosing Patents by a third party, Genentech must prove by a preponderance of the evidence that a direct infringer has used Kanjinti in performing every step of an Asserted Claim of the Dosing Patents.

1. Genentech's Position

Amgen confusingly recites only part of Genentech's inducement claim (recited in Instruction 5.3). Per below, Amgen erroneously suggests a Dosing Patent infringer must use Kanjinti exclusively.

2. Amgen's Position

In order to prove that Amgen induced infringement of the Dosing Patents, Genentech must first prove direct infringement. Therefore, the jury must be instructed on what findings it must make for direct infringement of the Dosing Patents.

VI. Proposed Instruction 5.3: Induced Infringement

A. Disputed Proposal 1

GENENTECH'S PROPOSAL: To find that Amgen induced infringement, it is not necessary to show that Amgen directly infringed the claims itself. AMGEN'S PROPOSAL: To find that Amgen induced infringement, it is necessary to show that someone directly infringes the claim itself.

1. Genentech's Position

Genentech's proposal follows *Orexo* and properly explains that Amgen may be liable without performing the claimed methods.

2. Amgen's Position

See Section VI.B.2.

B. Disputed Proposal 2

GENENTECH'S PROPOSAL: 1. A third party, such as a doctor or others working at the direction or under the control of a doctor, directly infringes that claim by performing each step of the claim; … In order to show a third party has directly infringed, Genentech must only prove that the third party performed all steps of the claimed method; it need not prove that all steps were performed with Kanjinti.
AMGEN'S PROPOSAL: 1. A third party, such as a doctor or others working at the direction or under the control of a doctor, directly infringes that claim by performing each and every step of the claim using Kanjinti;

1. Genentech's Position

Amgen encourages doctors to switch patients from Herceptin to Kanjinti because each switched patient results in a sale to Amgen. Amgen's attempt to insulate itself from liability is legally baseless.

First, Amgen is wrong to argue that all steps of the asserted methods of administering trastuzumab must be performed with Kanjinti. The law merely requires that the direct infringer perform all method steps, not that it use a particular trastuzumab product. *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1358 (Fed. Cir. 2012).

Second, encouragement is all that is necessary to support Amgen's intent, and infringement can be shown by circumstantial evidence. Causation as Amgen proposes it is inappropriate. *See* §VI.C.1.

Third, Amgen's suggestion that "[t]he only trastuzumab product whose use Amgen encourages is Kanjinti" does not mean Amgen is liable only when Kanjinti is used exclusively. Doctors who initially prescribe Herceptin and switch to Kanjinti complete the claimed method steps at Amgen's encouragement, which is sufficient for inducement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc) (inducement requires "that the alleged infringer's actions induced infringing acts").

2. Amgen's Position

To be liable for induced infringement, Amgen must have intended to and actually have caused a third party to directly infringe, which requires that third party to perform each and every step of a Dosing Patent claim. *See Exergen v. Wal-Mart Stores*, 575 F.3d 1312, 1320 (Fed. Cir. 2009). The only trastuzumab product whose use Amgen encourages and promotes is Kanjinti. Thus, Amgen must have specifically intended and caused a third party to carry out each and every requirement of a Dosing Patent claim using Kanjinti.

C. Disputed Proposal 3

AMGEN'S PROPOSAL: Amgen's alleged inducement, as opposed to other factors, actually caused the third party to perform each and every step of an Asserted Claim of a Dosing Patent.

1. Genentech's Position

Amgen inserts a notion of "causation" that is contrary to Federal Circuit precedent. A jury may find inducement where defendant has promoted infringement and without disproving other factors. "[I]f an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties." *DSU*, 471 F.3d at 1305-06. The Federal Circuit has "affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) ***without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material***." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016) (emphasis added). Genentech need only show that Amgen promoted infringing uses in materials communicated to customers. *See, e.g.*, *id*. at 1332–35 ("affirmative acts to induce third parties to import its products" sufficient to infer defendant "had induced its customers" to "infringe as a class"); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1220, 1222 (Fed. Cir. 2014) (advertisements); *Lucent Techs., Inc. v.*

Gateway, Inc., 580 F.3d 1301, 1323 (Fed. Cir. 2009) (user documentation); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) ("sales literature" and "manuals"); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F. 3d 1365, 1379 (Fed. Cir. 2001); *Moleculon Research Corp. v. CBS, Inc*., 793 F.2d 1261, 1272 (Fed. Cir. 1986) ("instruction sheet[s]" and "solution book[s]").

Genentech's proposal is consistent with *Power Integrations* and Amgen's is not. Amgen acknowledges that circumstantial evidence may be used to prove intent. Consistently, Genentech's instruction instructs the jury to consider Amgen's statements and actions. Amgen, in contrast, suggests a heightened causation requirement, that "other factors" must be excluded and "actually cause" a particular third party to infringe, which is not required. *See Power Integrations*, 843 F.3d at 1334-35 (rejecting requirement of evidence specifically connecting inducing acts to acts of direct infringement).

GlaxoSmithKline LLC v. Teva Pharm. USA, Inc., 313 F.Supp.3d 582, 591 (D. Del. 2018) is contrary to precedent and currently on appeal. *Dynacore Holding v. U.S. Philips*, 363 F.3d 1263 (Fed. Cir. 2004) does not support Amgen's heightened causation standard; it merely found patentee's infringement allegations lacking where the accused product had multiple uses and patentee offered no evidence the product was used for the infringing use. *Id.* at 1275-78.

2. Amgen's Position

Contrary to Genentech's arguments, *Power Integrations* held that causation is required. The court found that an instruction that "[direct] infringement need not have been actually caused by the [alleged inducer]'s actions … left the jury with the incorrect understanding that a party may be liable for induced infringement even where it does not successfully communicate with and induce a third-party direct infringer." *Power Integrations*, 843 F.3d at 1330-1331. "To prevail under a theory of indirect infringement, [plaintiff] must first prove that the defendants' actions led to direct infringement." *See id.* at 1332 (quoting *Dynacore Holding v. U.S. Philips*, 363 F.3d 1263, 1274 (Fed. Cir. 2004)). That "hard proof" of causation may not be necessary addresses the unremarkable proposition that the causation requirement can be proven with circumstantial evidence. *Power Integrations*, 843 F.3d at 1335; *see Dynacore*, 363 F.3d at 1274 ("[L]iability for indirect [induced] infringement must relate to the identified instances of direct infringement."); *GlaxoSmithKline LLC v. Teva Pharm. USA*, 313 F.Supp.3d 582, 591 (D. Del. 2018) (proof that defendant's "alleged inducement, ***as opposed to other factors,*** actually ***caused*** the physicians to directly infringe" is "an essential element"). *See also* Section VIII.B.

D. Disputed Proposal 4

AMGEN'S PROPOSAL: If you find that Amgen was aware of the Dosing Patents, but believed that the acts it encouraged did not infringe those patents, Amgen cannot be liable for inducement.

1. Genentech's Position

Amgen's statement of law is irrelevant. Amgen has not argued it believed others would not directly infringe the Dosing Patents. This would be baseless, as Amgen's label instructs all claimed steps. If Amgen newly makes such argument, it will implicate additional privilege waiver, prejudicing Genentech and requiring substantial discovery.

E. Disputed Proposal 5

AMGEN'S PROPOSAL: In order to establish active inducement of infringement, it is not sufficient that a third party itself directly infringes the claim. It is also not sufficient that Amgen knew of acts of direct infringement. Rather, in order to find induced infringement, you must find that Amgen specifically intended and caused the third party to carry out each and every requirement of an Asserted Claim of the Dosing Patents using Kanjinti.

1. Genentech's Position

Identifying what is *not* sufficient is redundant and confusing. *See also* §§VI.B-C.

2. Amgen's Position

See Sections VI.A-D.

F. Disputed Proposal 6

GENENTECH'S PROPOSAL: To find induced infringement, you must find that Amgen made statements or took actions directed to promoting or encouraging infringement, such as advertising an infringing use or instructing how to engage in

an infringing use. A product label may demonstrate intent to cause infringing acts if it encourages, recommends, or promotes an infringing use.

AMGEN'S PROPOSAL: To show induced infringement, it is not sufficient to show that the drug label permits an infringing use; permission is different from encouragement.

1. Genentech's Position

Genentech's proposal is accurate. *See HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 701-02 (Fed. Cir. 2019) (does "the proposed label encourage[], recommend[], or promote[] infringement"?); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059-60 (Fed. Cir. 2010); *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 915 (2005) ("active steps…to encourage direct infringement" including "advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent" to induce). It aids the jury by explaining what would (versus what would not) support a finding.

Amgen's proposal is misplaced. *HZNP* and *Shire* address labels that did not instruct every step of a claimed method and merely mentioned a step as permissible or not prohibited. That is not an issue here because the Kanjinti label instructs every step of the claimed regimen. Amgen does not argue why the permission doctrine should apply here; whether or not the legal doctrine applies is not a fact question for the jury. Amgen's instruction would improperly suggest

that label instructions are insufficient to show intent, if in addition to encouraging an infringing method, the label also discloses a separate method.

2. Amgen's Position

Amgen's proposal accurately states the law. *HZNP*, 940 F.3d at 701-02 (Fed. Cir. 2019) (no inducement of a method of treatment claim where the relevant drug's label did not affirmatively instruct and merely permitted, but did not require, a method step); *Shire*, 2014 WL 2861430 at *5-6 (D.N.J. Jun. 23, 2014) (granting summary judgment of no induced infringement where label stated that products may be taken "with or without food" because "permission is different from encouragement"); *In re Depomed Patent Litig.*, No. 13-4507, 2016 WL 7163647, at *63, *69 (D.N.J. Sept. 30, 2016) (no induced infringement where "label only instructs the user to administer the drug to treat severe chronic pain" generally as opposed to the claimed polyneuropathic pain; "even if the label permits administration for [an infringing use], permission is different from encouragement"). Whether it applies here, where the label includes unaccused treatment regimens is a question of fact for the jury.

VII. Proposed Instruction 5.4: Infringement By Filing Biologics License Application

GENENTECH'S PROPOSAL: It is an act of infringement to submit a Biologics License Application ("BLA") seeking FDA approval to commercially manufacture, use, or sell a biosimilar product that is claimed in a patent or the use of which is claimed in a patent before the expiration of such a patent. The determination of whether the product or proposed use of the product directly

infringes a claim or whether it demonstrates that the filer of the application would indirectly infringe the claim upon manufacture, use, or sale of the product is made based on the content of the BLA, including the instructions for use of the product (also called the "label" or "prescribing information") and the manufacturing process for the product that the applicant seeks approval to use. To show infringement by the submission of the BLA, Genentech must prove by a preponderance of the evidence that the prescribing information for which Amgen sought approval included instructions in its proposed label that will cause at least some users to infringe the asserted method claims of a Dosing Patent or the manufacturing process for which Amgen sought approval infringes a claim of the Kao Manufacturing Patent.

A. Genentech's Position

See §IV.

B. Amgen's Position

See Section IV.

VIII. Proposed Instruction 5.5: Determining Whether Third Parties Had an Implied License to Practice the Dosing Patents

[AMGEN'S PROPOSAL: One who owns a patent as patentee or assignee, having the right to exclude others from making, using, or selling what is claimed, may agree to let another do one or more of those acts. This is called a license, and the person allowed to do the set of acts is a licensee.

One type of license is an implied license. An implied license exists where (1) the patentee, through statements or conduct, gave an affirmative grant of consent or permission to make, use, or sell to the alleged infringers; (2) the alleged infringer relied on that statement or conduct; and (3) the alleged infringer would, therefore, be materially prejudiced if the patentee were allowed to proceed with a claim of infringement against the alleged infringer. The sale of a product without restriction grants an implied license to any patents owned by the seller of the product to which the parties might reasonably contemplate the product will be put.

If any third party, such as an oncologist, had an implied license from Genentech to practice any step of the Asserted Claims of the Dosing Patents, Amgen cannot be liable for induced infringement based on that third party's use of the Dosing Patents under the implied license from Genentech.]

[GENENTECH'S PROPOSAL: One who owns a patent as patentee or assignee, having the right to exclude others from making, using, or selling what is claimed, may agree to let another do one or more of those acts. This is called a license, and the person allowed to do the set of acts is a licensee.

The burden of proving that an implied license exists is on Amgen, as the party asserting an implied license as a defense to infringement.

An implied license is a form of implied-in-fact contract. In order to prove the defense of implied license, Amgen must establish by a preponderance of the evidence that (1) there was an existing relationship between Genentech and each direct infringer (such as a doctor, or person acting at the direction or under the control of a doctor) (2) within that relationship, Genentech transferred a right to use Kanjinti according to the method covered by the Dosing Patents; (3) Genentech transferred the right in exchange for some value from the direct infringer. Even where all the elements of implied license are met, they merely create a presumption of implied license which can be overcome by a clear indication of intent to the contrary.

You can only find an implied license if you find that Amgen has proven that a right to use Kanjinti according to the method covered by the Dosing Patents was granted to each direct infringer.]

A. Genentech's Position

Genentech has always contended that use of Kanjinti according to the claimed dosing regimen is infringement. Implied license is an affirmative defense, which Amgen has not pled and did not disclose during liability discovery. *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 878 (Fed. Cir. 1995). Amgen admits that this theory is a liability defense: *i.e.*, that "third part[ies]…do[] not directly infringe." It should be precluded as untimely. FRCP 8(c).

Because there has been no discovery on it, Amgen's implied license argument is unclear. What Amgen suggests here, for the first time, is contrary to the law. Any implied license extends to the product sold (Herceptin), not to a competitor's product (Kanjinti). *See Carborundum*, 72 F.3d at 879-80 (implied license only for life of product sold by patentee). Amgen also offers no authority that there can be an implied license to part of a method. Using Herceptin and Kanjinti to perform the patented method is outside the scope of any implied license and directly infringes.

Implied license is also an equitable defense for the Court. *Augustine Med., Inc. v. Progressive Dynamics, Inc.*, 194 F.3d 1367, 1370 (Fed. Cir. 1999); *TruePosition Inc. v. Andrew Corp.*, 568 F.Supp.2d 500, 509 (D. Del. 2008).

If such instruction is permitted over Genentech's objection, Genentech's proposal is neutral and accurate.

B. Amgen's Position

A third party with an implied license to practice one or more steps of the Dosing Patent claims does not directly infringe the Dosing Patents, which must be accounted for when calculating damages. Recent damages discovery suggests for the first time that Genentech will be asserting damages for dosing regimens where doctors used Herceptin rather than Kanjinti for recited steps in the asserted claims. Thus, Amgen raises the issue of implied license solely as a damages theory.

Damages discovery is ongoing—Genentech has yet to disclose its damages contentions and has never disclosed switched patients as infringing. Accordingly, Amgen is not time barred from raising implied license as part of its theory for the appropriate calculation of damages.

Any instruction on implied license should not be limited to the "right to use Kanjinti." When Genentech sells Herceptin, it grants an implied license for doctors to administer the loading dose as well as any subsequent does with Herceptin, satisfying at least the first limitation of every asserted Dosing Patent claim. Any doctor who then uses Kanjinti for subsequent doses would not satisfy at least the first limitation of the claims, and would not directly infringe.

Furthermore, *Carborundum* does not apply: the alleged direct infringers in *Caborundum* practiced the entire patent ***after*** switching from plaintiff's product to defendant's—that is not the case here. 72 F.3d at 875-76.

IX. Proposed Instruction 6.1: Invalidity Generally

AMGEN PROPOSAL: Amgen bears the burden of proving the invalidity of each Asserted Patent Claim by clear and convincing evidence.

A. Genentech's Position

See §X.A.

B. Amgen's Position

See Section X.A.

X. Proposed Instruction 6.2: Presumption of Validity

GENENTECH'S PROPOSAL:

Patents are issued by the Patent and Trademark office, often called the PTO. Issued patents are presumed to be valid. When a party challenges a patent's validity, the party bears the burden of demonstrating the PTO was wrong.

Because the law presumes issued patents are valid, Amgen bears the burden of proving the invalidity of each Asserted Claim by clear and convincing evidence.

A. Genentech's Position

Genentech accurately states the burden of proof and that Amgen must prove invalidity despite the PTO's validity finding. *Microsoft v. i4i*, 564 U.S. 91, 95 (2011). This instruction helps make clear why the burden regarding invalidity is different. *See LifeScan, Inc. v. Home Diagnostics, Inc.*, 103 F.Supp.2d 345, 377-78 (D. Del. 2000), *aff'd*, 13 F. App'x 940 (Fed. Cir. 2001). Amgen's cases support only that this instruction may be omitted, not that it should be.

B. Amgen's Position

Genentech's proposal is unnecessary, overstates Amgen's burden of proof, and may confuse the jury. The presumption of validity "is one of law, not fact, and does not constitute 'evidence' to be weighed against the challenger's evidence." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1358 (Fed. Cir. 2004) (affirming district court's decision not to include a jury instruction on the presumption of validity "because the jury applied the correct 'clear and convincing evidence' standard"). No instruction is necessary on the presumption of validity, where the

jury is instructed on the clear and convincing evidence standard—as Amgen proposes for Instruction 6.1. *See id.* As Judge Bryson recently held, instructing the jury to consider both the presumption of validity and the clear and convincing evidence standard could cause confusion without benefit because the instruction on the presumption of validity is unnecessary. *See Erfindergemeinschaft UroPep GbR v. Eli Lilly and Company*, No. 2:15-CV-1202, 2017 WL 959592 at *6 (E.D.Tex. Mar. 13, 2017) ("In the Court's judgment, the use of the phrase 'presumption of validity' would add little to the jury's understanding of the burden of proof on the validity issues."). The instruction should be excluded, and the Court should provide an instruction only on the clear and convincing evidence standard.

Moreover, Genentech misstates Amgen's burden of proof, which is to prove by clear and convincing evidence that the Asserted Patent Claims are ***invalid***, not that the PTO was wrong—Amgen is not required to address the PTO's findings.

XI. Proposed Instruction 6.3: Person of Ordinary Skill in the Art

A. Disputed Instruction 1

Whether a claim in a patent is invalid is determined from the perspective of [GENENTECH'S PROPOSAL: the hypothetical] [AMGEN'S PROPOSAL: a] person of ordinary skill in the art as of the priority date. The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art.

1. Genentech's Position

Obviousness is determined from the perspective of the hypothetical person of skill, not any one actual person (like Amgen's expert). *See, e.g.*, *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty., Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997) (POSA is "theoretical construct" not "some particular individual").

2. Amgen's Position

Genentech's duplicative recitations of "hypothetical" are unnecessarily repetitive.

B. Disputed Instruction 2

The person of ordinary skill is also a person of ordinary creativity who can use common sense to [GENENTECH'S PROPOSAL: fit the teachings of prior art together] [AMGEN'S PROPOSAL: solve problems in this field].

1. Genentech's Position

Genentech quotes *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402 (2007) (POSA "often will be able to fit the teachings of multiple patents together").

2. Amgen's Position

See F'Real Foods, LLC v. Hamilton Beach Brands, Inc., No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 22.

XII. Proposed Instruction 6.4: The Written Description Requirement

A. Disputed Proposal 1

GENENTECH'S PROPOSAL: A specification does not need to spell out every detail of the invention to satisfy the written description requirement and the exact words found in the claim do not need to be used. Nor are specific examples required. Only enough must be included in the specification to convey to the

person of ordinary skill in the art that the inventor possessed the full scope of the invention.

AMGEN'S PROPOSAL: A specification does not need to contain the exact words found in the claim to meet the written description requirement. Nor are specific examples required. The specification must convey to a person of ordinary skill in the art that the inventor actually possessed the full scope of the invention by the filing date of the claimed application.

1. Genentech's Position

Genentech tracks the AIPLA Model. Amgen incorrectly focuses on what "the inventor ***actually*** possessed." *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The law focuses on the POSA's understanding of the written description's disclosure, not the inventor's internal records. *Id.* ("possession" (versus disclosure) is not "very enlightening").

2. Amgen's Position

Amgen's proposal accurately states the law. *See Ariad*, 598 F.3d at 1349 (holding that "the written description requirement … requires that the specification objectively demonstrate that the applicant actually invented—was in possession of—the claimed subject matter").

B. Disputed Proposal 2

GENENTECH'S PROPOSAL: Amgen must prove by clear and convincing evidence that the specifications fail to meet the law's requirements for written description of an invention.

1. Genentech's Position

Repeating the applicable burden of proof aids the jury.

XIII. Proposed Instruction 6.5: The Enablement Requirement

GENENTECH'S PROPOSAL: Amgen has the burden of proving lack of enablement of a claim by clear and convincing evidence.

A. Genentech's Position

See §XII.B.

XIV. Proposed Instruction 6.6: Indefiniteness

GENENTECH'S PROPOSAL: It is Amgen's burden to prove by clear and convincing evidence that a person of ordinary skill in the art would not understand with reasonable certainty what is, and what is not, covered by the claims.

1. Genentech's Position

See §XII.B.

XV. Proposed Instruction 6.7: Prior Art and Public Use

A. Disputed Proposal 1

That which came before is referred to as the "prior art." Prior art can take the form of documents or things [AMGEN'S PROPOSAL: public knowledge, or public use.] AMGEN'S PROPOSAL: Any product or method that was publicly known or used by others in the United States before the claimed invention was invented AMGEN'S PROPOSAL: Any product or method that was in public use or on sale in the United States before the filing date of the patent, or before the priority date for the patent AMGEN'S PROPOSAL: Any method that was used by anyone before the named inventors' invention of the claimed method and that was not abandoned, suppressed, or concealed.

1. Genentech's Position

Amgen has not timely asserted invalidity based on public knowledge, public use, or prior inventorship. *See* D.I. 445. Beyond derivation and inventorship,

Amgen has suggested its public use/knowledge instructions are directed to a belatedly-disclosed invalidity theory from its expert's deposition testimony. Because such allegations are untimely, these instructions are inappropriate.

2. Amgen's Position

Amgen's proposal recites the statutory categories of prior art, any of which the jury may properly consider in evaluating Amgen's invalidity defenses. *See* 35 U.S.C. § 102 (Pre-AIA). Amgen has defenses based upon all of the listed categories, including Amgen's properly disclosed derivation and incorrect inventorship defenses. *See* Amgen's Opposition to Genentech's Motion to Strike (D.I. 456).

B. Disputed Proposal 2

[AMGEN'S PROPOSAL: Genentech does not assert an invention date prior to these priority dates.]

1. Genentech's Position

The instruction will identify the operative priority date. Amgen's proposal is argumentative and unnecessary.

2. Amgen's Position

As Genentech concedes in Footnotes 8 and 10, Genentech has neither asserted nor disclosed any invention date before the priority dates listed in Instructions 6.3 and 6.7.

C. Disputed Proposal 3

GENENTECH'S PROPOSAL: Amgen's burden of proof to show that the prior art renders a claim invalid never changes regardless of whether the U.S. Patent and Trademark Office considered the prior art. However, if the Patent Office considered a reference, it may be more difficult for Amgen to meet its burden of proof to prove invalidity based on that reference.

AMGEN'S PROPOSAL: The standard for assessing whether the prior art renders a claim invalid never changes regardless of whether the U.S. Patent and Trademark Office considered the prior art.

1. Genentech's Position

The Supreme Court held that the jury "most often should" be instructed on the import of the PTO's prior consideration of art. *i4i*, 564 U.S. at 111.

2. Amgen's Position

The Supreme Court in *Microsoft* neither approved nor required the instruction proposed by Genentech; rather, the Supreme Court stated that "a jury instruction on the effect of new evidence can, and when requested, most often should, be given." 564 U.S. at 111. Genentech's proposal risks juror confusion by overstating Amgen's burden of proof.

XVI. Proposed Instruction 6.8: Anticipation

AMGEN'S PROPOSAL: In particular, Hellmann, *Treatment with Anti-ErbB2 Antibodies*, United States Patent No. 8,309,087, issued November 13, 2012, filed May 9, 2011, claiming priority to application No. 09/209,023, filed December 10, 1998, incorporates by reference Perry (Ed.), *The Chemotherapy Source Book* (1992), and the combination of the two is treated as a single disclosure under the law.

1. Genentech's Position

Whether Perry incorporates Hellman is a disputed issue of law for resolution before trial.

2. Amgen's Position

The agreed-upon instruction states that the Court will specifically instruct the jury if one reference incorporates another by reference; including here the references to which this issue applies will assist the jury.

XVII. Proposed Instruction 6.9: Obviousness

A. Disputed Proposal 1

[GENENTECH'S PROPOSAL: A claim is not proved obvious merely by demonstrating that each of the elements was independently known in the prior art.] Thus, in considering whether a claimed invention is obvious, you should consider whether at the time of the claimed invention there was a reason that would have prompted the person of ordinary skill in the art to combine the known elements in a way the claimed invention does.

1. Genentech's Position

Genentech tracks the AIPLA Model and Supreme Court precedent. *See* AIPLA Model §7.2 (2018); *KSR*, 550 U.S. at 418.

B. Disputed Proposal 2

AMGEN'S PROPOSAL: Obviousness does not require absolute predictability, although at least some degree of predictability is required. There is no law-required minimum showing for a "reasonable expectation of success."

1. Genentech's Position

Amgen's addition is confusing, unnecessary, and misleading. The agreed-to instruction accurately identifies the required "reasonable" expectation of success.

Instructing that no "minimum" is required by "law" risks confusion about that standard or suggests any de minimis showing suffices.

2. Amgen's Position

Amgen's proposal accurately states the law. *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc*., 903 F.3d 1310, 1333 (Fed. Cir. 2018) (noting the absence of legal support for "a law-required minimum" showing necessary to "support a 'reasonable' expectation of success"); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("the expectation of success need only be reasonable, not absolute").

C. Disputed Proposal 3

You must put yourself in the place of [GENENTECH'S PROPOSAL: the hypothetical] [AMGEN'S PROPOSAL: a] person of ordinary skill in the art as of the patent's priority date.

1. Genentech's Position

See §XI.A.1.

2. Amgen's Position

See Section XI.A.2.

D. Disputed Proposal 4

GENENTECH'S PROPOSAL: These objective indicia should be considered along with all the other evidence in the case in determining whether the claimed invention would have been obvious. However, there must be a connection between the secondary consideration and the claimed invention if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue.

AMGEN'S PROPOSAL: These objective indicia are relevant to obviousness only if there is a connection, or nexus, between them and the invention covered by the patent claims. For example, commercial success is relevant to obviousness only if the success of the product is related to a feature of the patent claims. If the commercial success is the result of something else, such as innovative marketing, and not to a patented feature, then you should not consider it to be an indication of non-obviousness. Likewise, if the commercial success is a result of another patent that prevented others from trying or implementing an obvious idea, then you should not consider commercial success to be an indication of non-obviousness.

1. Genentech's Position

Genentech's proposal accurately describes nexus. Instructing on Amgen's contentions (without Genentech's) is prejudicial.

Amgen is incorrect that if commercial success is caused by multiple factors, it *cannot* be considered. *See Acorda*, 903 F.3d at 1338 ("blocking patents" do not "necessarily detract from evidence of commercial success"). Those other factors merely go to the *weight* of the commercial success evidence. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd*., 851 F.2d 1387, 1393 (Fed. Cir. 1988).

2. Amgen's Position

Amgen's proposal accurately states the law. *See, e.g.*, *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013) ("Where market entry by others was precluded [due to blocking patents], the inference of non-obviousness of [the asserted claims], from evidence of commercial success, is weak.").

XVIII. Proposed Instruction 6.10-6.11: Derivation and Incorrect Inventorship

A. Disputed Proposal 1

GENENTECH'S PROPOSAL (6.10 Derivation): Conception requires more than a general goal or research plan; rather, it requires a definite and permanent, specific, settled idea encompassing all limitations of the claims. Communication of the conception to an inventor named in the patent must be sufficient to enable the person of ordinary skill in the art to implement the invention.

AMGEN'S PROPOSAL (6.10 Derivation): For derivation, there is no requirement that the "communication" of the conception to the named inventor occur in the United States. Derivation may be of the claimed invention itself or of an obvious variation of the invention. If an inventor named on a patent derived the patented invention from someone else, then the patent claims covering the invention are invalid.

GENENTECH'S PROPOSAL (6.11 Incorrect Inventorship): The patent laws also require that the patent correctly name each and every inventor who contributed to the claimed invention. To prove incorrect inventorship, Amgen must prove by clear and convincing evidence that the alleged co-inventor(s) conceived of one or more limitations that is not insignificant in quality as compared to the full invention. It is not enough if the alleged co-inventor merely explained to the named inventors well-known concepts and/or the current state of the art.

AMGEN'S PROPOSAL (6.11 Incorrect Inventorship): The patent laws also require that the patent correctly name each and every inventor who contributed to any of the claimed invention. For incorrect inventorship, unlike derivation, the alleged co-inventor(s) need not have conceived of the claimed invention as a whole, but rather need only have conceived of a single limitation of the claimed invention. A patent is invalid if it fails to correctly name each and every inventor who contributed to any limitation of the claimed invention.

1. Genentech's Position

Genentech objects to including any derivation or incorrect inventorship instruction because those defenses are untimely. *See* D.I. 445; 10/16/2019 Hearing

Tr. 195:18-208:3 (denying motion to compel because Amgen's defense was untimely).

If any instructions were nevertheless given, Genentech's proposals are more accurate. *See Cumberland Pharms. Inc. v. Mylan Institutional LLC*, 846 F.3d 1213, 1218 (Fed. Cir. 2017) (derivation), and *Gambro Lundia AB v. Baxter Healthcare Corp*., 110 F.3d 1573, 1576 (Fed. Cir. 1997) (rejecting that derivation "incorporate[s] a determination of obviousness"); *Pannu v. Iolab Corp*., 155 F.3d 1344, 1351 (Fed Cir. 1998) (inventorship).

2. Amgen's Position

Amgen's defenses were adequately and timely disclosed (D.I. 456).

Amgen's proposal on derivation is consistent with the Manual of Patent Examining Procedure at § 2137; *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. App. 1981) ("[T]he site of derivation need not be in this country to bar a deriver from patenting the subject matter"); and ABA Model Patent Jury Instruction 10.7. Amgen's proposal on inventorship is an accurate statement of the law. *See Pannu*, 155 F.3d at 1351 (no requirement that a co-inventor "make a contribution to the subject matter of every claim of the patent"); 35 U.S.C. §102(f) (pre-AIA); Manual of Patent Examining Procedure §2137.

B. Disputed Proposal 2

Amgen contends that, [AMGEN'S PROPOSAL**:** to the extent the Asserted Claims of the Dosing Patents recite any invention at all,] the Dosing Patents fail to name Dr. Brian Leyland-Jones as an inventor.

1. Genentech's Position

Amgen's proposal is unnecessary and argumentative.

C. Disputed Proposal 3

GENENTECH PROPOSAL: The listing of inventors on a patent is presumed to be correct.

1. Genentech's Position

See §X.A; *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301 (Fed. Cir. 2002).

2. Amgen's Position

See Section X.B.

D. Disputed Proposal 4

AMGEN'S PROPOSAL (6.10 Derivation): Amgen contends that no later than March 1999, Dr. Leyland-Jones conceived of the idea to prescribe Herceptin at an initial dose of 8 mg/kg and a plurality of subsequent doses at 6 mg/kg, each dose given every three weeks, as claimed in the Dosing Patents. Amgen also contends that Dr. Leyland-Jones communicated his conception of the dosing regimens recited in the Asserted Claims of the Dosing Patents to named inventor Dr. Sharon Baughman. AMGEN'S PROPOSAL (6.11 Incorrect Inventorship): Specifically, Amgen contends that no later than March 1999, Dr. Leyland-Jones conceived of the idea to prescribe Herceptin at an initial dose of 8 mg/kg and a plurality of subsequent doses at 6 mg/kg, each dose given every three weeks, as claimed in the Dosing Patents.

1. Genentech's Position

Presenting Amgen's arguments (without Genentech's) is prejudicial, without aiding the jury in understanding the law.

2. Amgen's Position

Amgen proposes including certain fact-specific contentions to clarify for the jury the factual issues related to the instruction. Amgen has indicated these contentions in grey shading to assist the Court in identifying the portions of the jury instructions to which this proposal applies.

E. Disputed Proposal 5

AMGEN'S PROPOSAL (6.10 Derivation): If you find that Amgen has proved by clear and convincing evidence that the named inventors on the Dosing Patents derived the invention covered by the Asserted Claims of the Dosing Patents from Dr. Leyland-Jones, then you must find that the Asserted Claims of the Dosing Patents are invalid. AMGEN'S PROPOSAL (6.11 Incorrect Inventorship): If you find that Amgen has proved by clear and convincing evidence that someone other than Dr. Baughman or Dr. Shak contributed to any limitation recited in the Asserted Claims of the Dosing Patents, then you must find that the Asserted Claims of the Dosing Patents are invalid.

1. Genentech's Position

Amgen's proposals are redundant of the prior sentences that states the burden.

Amgen is wrong that incorrect inventorship requires invalidity; Genentech may correct inventorship. 35 U.S.C. §256; *Trovan,* 299 F.3d at 1301, 1350-51.

2. Amgen's Position

Amgen's proposal will assist the jury in understanding the requirements for derivation.

Unless Genentech invokes and satisfies the criteria of 35 U.S.C. §256, a finding that someone other than the listed inventors was an inventor invalidates the patent. *Pannu*, 155 F.3d at 1349 (discussing §256); Manual of Patent Examining Procedure §2137.

XIX. Proposed Instruction 6.12: Inequitable Conduct

AMGEN'S PROPOSAL: Amgen contends that Genentech may not enforce the Kao Manufacturing Patent against Amgen because Genentech engaged in inequitable conduct before the Patent and Trademark Office when it obtained the Kao Manufacturing Patent. To prove that inequitable conduct occurred, Amgen must prove by clear and convincing evidence that the patent applicant or the applicant's attorney or representative withheld or misrepresented material information, and did so with an intent to mislead or deceive the Patent and Trademark Office.

A. Amgen's Position

Proposal withdrawn.

XX. Proposed Instruction 7.1: Damages – Generally

If you find that Amgen infringes any of the Asserted Patent Claims, and that those claims are not invalid [AMGEN'S PROPOSAL: or unenforceable], you must determine the amount of damages to be awarded Genentech for Amgen's infringement. On the other hand, if you find that each of the Asserted Patent Claims is either invalid, not infringed, [AMGEN'S PROPOSAL: or unenforceable], then you should not consider damages in your deliberations.
[…]
You will need to address damages only if you find that one or more of the Asserted Patent Claims are infringed, not invalid [AMGEN'S PROPOSAL: and not unenforceable].

1. Amgen's Position

Proposal withdrawn.

XXI. Proposed Instruction 7.2: Kinds of Damages That May Be Recovered

A. Disputed Proposal 1

AMGEN'S PROPOSAL: Lost profits are limited to that portion of Herceptin's profits that are reasonably allocated to the infringed method patents, not to the entire profits of Genentech's Herceptin. The entire profits of Herceptin consist of the combined value of non-patented features of Herceptin, such as the antibody itself and its therapeutic effect, which are no longer patented, and the allegedly infringed patented method of dosing at 8 mg/kg initially followed by 6 mg/kg every three weeks, and the method for preventing disulfide bond reduction during the manufacturing process. If you award lost profits, the lost profits damages must be limited to that portion of Genentech's lost profits actually attributable to Amgen's direct or induced infringement of Genentech's patented methods. Additionally, if you award lost profits, the lost profits damages must be limited only to lost profits that Genentech proved are caused by Amgen's infringement of Genentech's patented methods, rather than sales of Kanjinti that were put to non-infringing uses, or lost profits due to the activities of third parties, such as Genentech's licensees, who began selling trastuzumab biosimilar products on December 1, 2019."

[. . .]

In deciding whether to award damages, and what type of damages to award, you must separately consider the appropriate damage awards for infringement occurring before other competing trastuzumab biosimilars were available on the market (before December 1, 2019) and infringement occurring after other competing trastuzumab biosimilars were available on the market (after December 1, 2019).

1. Genentech's Position

Genentech uses the AIPLA Model.

Amgen's proposal is confusing, unnecessary, argumentative, and contrary to law. Amgen introduces apportionment concepts unrelated to this instruction, and

its lost-profits-apportionment theory is incorrect. *See* §XXII.A. If any apportionment instruction is proper, it should be in Instruction 7.3.

Amgen's reference to when "other competing trastuzumab biosimilars were available on the market" is improper advocacy and does not state applicable law.

2. Amgen's Position

As explained below, apportionment is required in this case regardless of the kind of damages sought. *See* Section XXII.B. The trastuzumab market transitioned from a two-player market to a multi-player market when Mylan launched December 2, 2019, thus changing its market dynamics. These explanations will assist the jury to understand the damages issues to be resolved.

B. Disputed Proposal 2

A reasonable royalty is the amount that someone wanting to use the patented [GENENTECH'S PROPOSAL: invention][AMGEN'S PROPOSAL: process or method] would have agreed to pay to the patent owner and the patent owner would have accepted.

1. Genentech's Position

"Invention" succinctly captures the process, method, and product-made-by-patented-process claims at issue. *See* §III.A.

2. Amgen's Position

The Patents-in-Suit are directed only to processes or methods, there is no accused product. Put differently, Kanjinti itself is not covered by any Patent-in-Suit. Thus, Amgen's proposal explains how to calculate damages for infringement

of a process or method when the only sales made by Amgen are sales of a product not itself covered by the Patents-in-Suit.

XXII. Proposed Instruction 7.3: Attribution/Apportionment & Proposed Instruction 7.16: Reasonable Royalty – Attribution/Apportionment

AMGEN'S PROPOSAL 7.3: The amount you find as damages must be based on the value attributable to the patented methods, as distinct from other, unpatented features, such as the product itself, marketing or advertising, or the manufacturer's size or market position. Genentech must separately calculate, that is apportion, the amount of its money damages between that which is attributable to use of the patented methods and that which is attributable to the unpatented features. Calculating damages may involve estimating the value of a feature that may not have ever been individually sold. The evidence provided by Genentech for this apportionment must be reliable and tangible, and not hypothetical or speculative.

Alternately, in order to establish that Genentech's lost profits and damages should be calculated on the entire value of Herceptin, Genentech must show, by equally reliable evidence, that the either entire value of Herceptin is attributable to administering trastuzumab using the methods of the Dosing Patents, or that the entire value of Herceptin is attributable to manufacturing trastuzumab using method of the Kao Manufacturing Patent.

If you award lost profits or price erosion damages, the amount of lost profits or price erosion damages awarded must be tied to Genentech's profits attributable to its patented methods, and must not include profits attributable to other aspects of Herceptin. The lost profits damages must be limited to that portion of Genentech's lost profits actually attributable to Amgen's direct or induced infringement of Genentech's patented methods.

If you award a reasonable royalty on Amgen's sales of Kanjinti, in determining the appropriate royalty base (that is, the amount of sales to which the royalty rate applies), and the appropriate royalty rate, the ultimate combination of both the royalty rate and the royalty base must reflect the value attributable to the patented methods. In other words, the royalty base must be closely tied to the claimed invention. It is not sufficient to use a royalty base that is too high and then adjust the damages downward by applying a lower royalty rate. Similarly, it is not appropriate to select a royalty base that is too low and then adjust it upward by applying a higher royalty rate. Rather, you must determine an appropriate base and

an appropriate royalty rate that reflect the value attributable to the patented methods alone.

GENENTECH'S PROPOSAL 7.16

The amount you find as damages must be based on the value attributable the patented technology, as distinct from other, unpatented features or other factors such as marketing or advertising, or Amgen's size or market position. You must determine an appropriate reasonable royalty that reflects the value attributable to the patented invention alone.

A. Genentech's Position

Amgen's instruction on attribution/apportionment is not in any model instructions for good reason. It is contrary to Federal Circuit precedent regarding lost profits. The Federal Circuit has declined to apportion damages when *Panduit* is satisfied, as "*Panduit*'s requirement that patentees prove demand for the product as a whole and the absence of non-infringing alternatives ties lost profit damages to specific claim limitations and ensures that damages are commensurate with the value of the patented features." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1288 (Fed. Cir. 2017); *id.* at 1290 ("when the *Panduit* factors are met, they incorporate into their very analysis the value properly attributed to the patented feature"). Indeed, Amgen acknowledges that "application of *Panduit* factors can result in proper apportionment." If the jury agrees, that will satisfy apportionment principles. *Id.* ("When a patentee proves it is entitled to recover lost profit damages ... it is entitled to be made whole for the injuries it suffered.").

Amgen attempts to distinguish *Mentor Graphics* because it involved an "undisputed record" that the *Panduit* factors were satisfied. But Genentech intends to prove lost profits under *Panduit* here. The fact that Amgen contests whether Genentech can satisfy *Panduit* is not a reason to require additional apportionment for the lost profits that Genentech seeks under *Panduit.* Nor is *Mentor Graphics* limited to its facts; *Mentor Graphics* addressed apportionment for lost profits under *Panduit* generally, as the prior quotations show. The Federal Circuit left open only "whether a different theory of 'but for' damages"—i.e., not based on *Panduit*—"adequately incorporates apportionment principles." *Id.* at 1288.

Amgen's authorities are inapt. *Exmark*, *AstraZeneca*, and *Ericsson* analyze apportionment for reasonable royalties, not lost profits. *WesternGeco* suggests in dicta that there may be situations where further apportionment is necessary "[i]f the application of the *Panduit* factors does not result in the separation of profits attributable to the patented device." 913 F.3d at 1073. But *WesternGeco* was addressing lost profits where the patentee did not sell a directly competing product; the patentee only sold services utilizing its patented product. *Id.* at 1070. *WesternGeco*'s suggestion that *Panduit* may not adequately separate the profits attributable to the inventions in those unique circumstances has no application here where the parties sell directly competing products used to practice the invention. There is also no authority for Amgen's statement that "whether or not the *Panduit*

factors result in proper apportionment is a fact question." This suggestion is illogical; it is not for the jury to decide what test to apply.

Amgen erroneously suggests the entire market value rule is a prerequisite to obtaining *lost profits*. It is an "exception" to the apportionment rule for a *reasonable royalty* analysis. *LaserDynamics, Inc. v. Quanta Comput.*, 694 F.3d 51, 66-67 (Fed. Cir. 2012).

Amgen's royalty instruction duplicates Instruction 7.16.

B. Amgen's Position

All damages—whether lost profits or a reasonable royalty—must be apportioned to reflect the value that is attributable to the valid, infringed patents. *See, e.g.*, *Garretson v. Clark*, 111 U.S. 120, 121 (1884) ("The patentee … must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features"); *WesternGeco L.L.C.*, 913 F.3d at 1073-1075 ("If the application of the *Panduit* factors does not result in the separation of profits attributable to the patented device and the profits attributable to providing other aspects of the surveys … it appears that apportionment is necessary."); *Mentor Graphics v. EVE*, 870 F.3d 1298, 1299 (Fed. Cir. 2017) (denying petition for rehearing en banc) ("[W]here an infringing product is a multi-component product with patented and unpatented components, apportionment is required."); *Mentor Graphics*, 851 F.3d

at 1287-88 ("[A]pportionment is an important component of damages law generally, and we believe it is necessary in both reasonably royalty and lost profits analysis."); *Ericsson v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) ("Apportionment is required even for non-royalty forms of damages.").

Although application of the *Panduit* factors can result in proper apportionment, whether application of the *Panduit* factors does result in proper apportionment is a fact-dependent inquiry. *See WesternGeco*, 913 F.3d at 1073 ("If the application of the *Panduit* factors does not result in the separation of profits attributable to the patented device and the profits attributable to providing other aspects of the surveys … it appears that apportionment is necessary"); *Mentor Graphics*, 851 F.3d at 1288 ("[O]n the undisputed facts of this record, satisfaction of the *Panduit* factors satisfies principles of apportionment."). Because whether the *Panduit* factors result in proper apportionment is a fact question, the jury must be instructed on how to make that assessment.

Genentech's reliance on *Mentor Graphics*' statement that "satisfaction of the *Panduit* factors satisfies principles of apportionment" is misplaced. The Federal Circuit's holding was based on an undisputed factual record "that for each infringing sale [defendant] made to Intel, Mentor lost that exact sale," making the *Mentor Graphics* case "quite narrow and unlike the complicated fact patterns that impact so many damages models in patent cases." *Id.* at 1286. Amgen has made

no similar concession here. Whether the *Panduit* factors satisfied apportionment on *Mentor Graphics*' "quite narrow" facts says nothing about whether application of the *Panduit* factors will result in proper apportionment of any lost profits Genentech seeks. *See id.* at 1288 ("We leave for another day whether a different theory of 'but for' damages adequately incorporates apportionment principles."); *WesternGeco*, 913 F.3d at 1073.

The need for an instruction on apportionment of lost profits is particularly important here, because Genentech has conceded that patents other than the Dosing Patents or the Kao Manufacturing Patent are significant drivers of the consumer demand for, and commercial success of, Herceptin. Accordingly, neither the Dosing Patents nor the Kao Manufacturing Patent satisfies the Entire Market Value Rule, as would be required to avoid apportionment.

For example, Genentech stated in proceedings before the Patent Office that the Carter '213 patent and the Cabilly '415 patent—two patents Genentech initially asserted against Amgen, which expired before Kanjinti's commercial launch—were responsible for Herceptin's commercial success. *See Celltrion v. Genentech*, IPR2017-01373, Patent Owner's Preliminary Response, D.I. 165 at 65 (P.T.A.B. 2017) ("Some of Genentech's most successful antibodies embody the claims of the '213 patent, including Herceptin… The success of these drugs is attributable, in part, to their unique amino acid sequences provided using the '213 patent's

consensus sequence approach."); *Sanofi-Aventis v. Genentech*, IPR2015-01624, Patent Owner's Response, D.I. 31 at 62 (P.T.A.B. 2015) ("[S]ome of Genentech's most successful products embody the Cabilly '415 patent, including several 'blockbuster' drugs… There is a direct nexus between the commercial success of those products and the challenged claims; each is produced using the claimed single host co-expression."). Because Genentech has conceded that the entire value of Herceptin is not attributable to the Patents-in-Suit, the jury must be instructed on apportionment for all damages.

XXIII. Proposed Instruction 7.4: Lost Profits – "But-For" Test

GENENTECH'S PROPOSAL: It is important to remember that the profits I have been referring to are the profits allegedly lost by Genentech, not the profits, if any, made by Amgen on the allegedly infringing sales.
AMGEN'S PROPOSAL: It is important to remember that the profits I have been referring to are the profits allegedly lost by Genentech to Amgen's alleged infringement of the patented methods, not the profits Genentech may have lost to sales of competing trastuzumab biosimilars after December 1, 2019, and not the profits, if any, attributable to non-patented uses or features of Genentech's products. Lost profits are not the profits made by Amgen as a result of its alleged infringement of Genentech's patented methods.

A. Genentech's Position

Genentech uses the AIPLA Model. *See* §§VII.A, XXI.B, XXII.

B. Amgen's Position

In determining lost profits using the "but-for" test, the jury must incorporate principles of apportionment, as well as account for the "but-for" world before and after Mylan's entry. *See* Sections XXI.A.2. and XX.II.B.

XXIV. Proposed Instruction 7.5: Lost Profits – Factors

Genentech is entitled to lost profits [AMGEN'S PROPOSAL: only] if you find that Genentech has proven each of the following factors by a preponderance of the evidence, the more likely than not standard.

[…]

AMGEN'S PROPOSAL: for Genentech to recover lost profits based on the Herceptin product for Amgen's alleged inducement of others to infringe the Dosing Patents, Genentech must prove that the patented method of dosing at 8 mg/kg initially followed by 6 mg/kg every three weeks (i) drove customer demand for Kanjinti, (ii) that customers would not have purchased Kanjinti if it were only available for use in accordance with non-infringing methods of administration, (iii) that Genentech possessed the marketing and manufacturing ability to satisfy all market demand for trastuzumab, and (iv) that Genentech carried its burden of proving the actual amount of its lost profits that was attributable to Amgen's inducement of others to infringe the Dosing Patents.

Similarly, for Genentech to recover lost profits of the Herceptin product for Amgen's alleged infringement of the Kao Manufacturing Patent, Genentech must prove that the patented method for preventing reduction of disulfide bonds during manufacturing (i) drove customer demand for Kanjinti, (ii) that customers would not have purchased Kanjinti if it were manufactured with a non-infringing method, (iii) that Genentech possessed the marketing and manufacturing ability to satisfy all market demand for trastuzumab, and (iv) that Genentech carried its burden of proving the actual amount of its lost profits that were attributable to Amgen's infringement of the Kao Manufacturing Patent.

If you find that Genentech has proven each of these requirements, you must additionally decide (i) whether Genentech has proven the extent of use of its patented methods, and limited its claims to lost profits that were actually caused by Amgen's use of Genentech's patented methods, as opposed to other reasons, and (ii) whether Genentech has adequately apportioned the profits it made on sales of its products to isolate profits attributable to its patented methods from profits attributable to non-patented components of Genentech's products.

A. Genentech's Position

Amgen's improper, argumentative additions to the AIPLA Model are unnecessary; subsequent instructions explain each *Panduit* factor. Amgen also

misstates the law, including by adding that the patented invention must "drive" demand for Kanjinti. The proper "demand" analysis "considers demand for the product as a whole." *Mentor Graphics*, 851 F.3d at 1285. Amgen's inducement language is redundant of separate instructions. *See* §XXII.A.

B. Amgen's Position

In this case, where Kanjinti is not covered by any Patent-in-Suit, additional explanation of how to calculate damages based on the Patents-in-Suit will assist the jury. Additionally, in determining lost profits, the jury must incorporate principles of apportionment. *See* Sections XXI.A.2. and XX.II.B.

XXV. Proposed Instruction 7.7: Lost Profits – Acceptable Non-Infringing Substitutes

A. Disputed Proposal 1

AMGEN'S PROPOSAL: A non-infringing substitute may be one that involved modification of the method of manufacture or method of administering Kanjinti to avoid infringement, or the removal of at least one feature of the Asserted Patent Claims from the process of manufacturing Kanjinti or method of administering Kanjinti.

1. Genentech's Position

Amgen's proposal is argumentative, unnecessary, and confusing. It assumes any modification to a patented method would be a non-infringing substitute. Modifying a method to be non-infringing does not necessarily make it an *acceptable* substitute. *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1355 (Fed. Cir. 1999).

2. Amgen's Position

Amgen's proposal is consistent with AIPLA Model Jury Instruction 10.2.1.4 on "Acceptable Non-Infringing Substitutes."

B. Disputed Proposal 2

AMGEN'S PROPOSAL: Even if you find that Genentech's and Amgen's products were the only ones with the advantages of the patented invention, Genentech is nonetheless required to prove to you that it, in fact, would have made the infringing sales of Kanjinti.

1. Genentech's Position

Amgen's argumentative proposal is unnecessary because it does not define non-infringing alternatives. Instruction 7.4 describes the "but-for" test.

2. Amgen's Position

Amgen's proposal is consistent with AIPLA Model Jury Instruction 10.2.1.4 on "Acceptable Non-Infringing Substitutes."

XXVI. Proposed Instruction 7.8: Lost Profits – Market Share

[GENENTECH'S PROPOSAL: If you find that there were acceptable non-infringing substitutes in the market, then Genentech may be entitled to lost profits on a portion of Amgen's sales of Kanjinti. The burden is on Genentech to prove that it would have made some, but not all, of Amgen's sales but for the infringement by proving Genentech's share of the market in which the infringing product is sold, excluding infringing products. Genentech may show that it is more likely than not that Herceptin competed in the same market as Kanjinti, and that Genentech would have made a portion of the infringing sales equal to at least Genentech's share of that market but for Amgen's infringement. It is not necessary for Genentech to prove that Genentech and Amgen were the only two suppliers in the market for Genentech to demonstrate entitlement to lost profits. The burden is on Genentech, however, to show that it is more likely than not that it would have sold that portion had Kanjinti never existed.]

[AMGEN'S PROPOSAL: If you find that there were acceptable non-infringing alternative methods of administering trastuzumab (for the Dosing Patents) or non-infringing methods to prevent reduction of disulfide bonds in the manufacture of trastuzumab (for the Kao Manufacturing Patent), you must account for them in deciding whether to award Genentech lost profits. This includes accounting for the portion of sales of Kanjinti that could be manufactured or administered without using the patented methods, as well as portion of sales that could have been sold by the companies that Genentech has licensed under the Patents-in-Suit. The burden is on Genentech to prove by a preponderance of the evidence the extent to which its share of the market for trastuzumab would be larger than it is today if it competed against the companies it has licensed under the Patents-in-Suit and Amgen, if Amgen neither infringed the methods covered by the Patents-in-Suit nor induced others to do so.

For the Kao Manufacturing Patent, this means that Genentech must show, but for Amgen's use of the method of manufacture of the Asserted Claims of the Kao Manufacturing Patent, the extent to which Genentech would have a larger share of the market for trastuzumab if it competed against the companies it has licensed under the Patents-in-Suit and Amgen's Kanjinti manufactured using a non-infringing alternative method to prevent reduction of disulfide bonds .

For the Dosing Patents, this means that Genentech must show that, but for Amgen's inducement of physicians to administer Kanjinti according to the Asserted Claims of the Dosing Patents, the extent to which Genentech would have a larger share of the market for trastuzumab if it competed against the companies it has licensed under the Patents-in-Suit and Amgen's Kanjinti for use with non-infringing alternative methods of administering trastuzumab.

In making this determination, you must separately consider whether Genentech has proven its entitlement to any lost profits for the period of time when only Amgen was in the market (before December 1, 2019), and for the period of time after the companies that Genentech has licensed under the Patents-in-Suit began competing in the market with Genentech and Amgen (after December 1, 2019), and factor out of your analysis any profits that Genentech lost as a result of competition from its licensees.]

A. Genentech's Position

Genentech's neutral instruction is from model instructions.

Amgen's instruction regarding the Dosing Patents is misleading. Lost profits may be awarded for *all* profits that Genentech lost due to Amgen's infringement. Thus, the correct construction of the but-for world is one in which "the infringement had not occurred," *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 US 476, 507 (1964); *see also GlaxoSmithKline LLC v. Glenmark Pharms. Inc.*, 2017 WL 8948975, at *4 (D. Del. May 30, 2017) (In case against generics manufacturer related to method of administering drug, finding "[t]he 'but for' inquiry requires a reconstruction of the market as it would have developed absent the infringing product....").

Amgen's proposal also repeats elements from previous instructions and prejudicially introduces Amgen's arguments.

B. Amgen's Position

In this case, where Kanjinti is not covered by the Patents-in-Suit, further explanation—including the facts shown in grey specific to the Dosing Patents and the Kao Manufacturing Patent—will assist the jury to understand how to calculate Genentech's market share in the "but-for" world. *See also* Sections XXI.A.2 and XXI.B.2.

XXVII. Proposed Instruction 7.10: Lost Profits – Amount of Profit

AMGEN'S PROPOSAL: To the extent you find that Amgen has induced infringement of the Dosing Patents, Genentech may receive damages only for sales that led to an act of direct infringement. In order to establish the amount of its lost profits, Genentech must show the connection between a sale of Kanjinti for which

Genentech claims it has lost profits and Amgen's induced infringement that led to direct infringement of its Dosing Patents.

Additionally, for each sale for which Genentech claims lost profits based on induced infringement, Genentech must show by a preponderance of the evidence that Amgen's inducement of patent infringement, and not other factors such as Genentech's drug label or treatment guidelines published by others, caused the third party to directly infringe the Dosing Patents.

Genentech's lost profits damages award must further be limited to that portion of the lost profits of Herceptin actually attributable to the patented method of dosing at 8 mg/kg initially followed by 6 mg/kg every three weeks and/or the method of preventing disulfide bond reduction during manufacture. You must undertake this analysis separately for the time period before other competing biosimilar trastuzumab products were available on the market (before December 1, 2019) and the time period after other competing biosimilar trastuzumab products were available on the market (after December 1, 2019).

Even if you find that Amgen both directly infringed the Kao Manufacturing Patent and induced others to infringe one or more of the Dosing Patents, if you conclude that Genentech is entitled to lost profits on the entire sale of Herceptin, you can award Genentech the lost profits only once on each sale of Herceptin to a particular customer.

If you find that Genentech has not met its burden to demonstrate by a preponderance of the evidence the amount of profits lost due to Amgen's direct or induced infringement, you may not award lost profits.

A. Genentech's Position

Genentech's neutral instruction is from the AIPLA Model.

Amgen's proposal is one-sided, incorrect (*see* §XXII.A), and confusing because inducement is instructed separately.

B. Amgen's Position

Apportionment is required for lost profits. *See* Section XXII.B (Apportionment). Furthermore, any lost profits based on the Dosing Patents must

be limited to the extent of Amgen's inducement of direct infringement of the Dosing Patents. *See* Section VI (Induced Infringement).

XXVIII. Proposed Instruction 7.11: Price Erosion

AMGEN'S PROPOSAL: Genentech must prove that it lowered its prices, or did not raise them, because of the induced or direct infringement by Amgen, and not for some other reason. Specifically, if Genentech would have lowered its prices in response to Amgen's sales of Kanjinti for non-infringing uses or in response to Amgen's sales of Kanjinti that did not use or include on the label the patented methods, or for any other reason, that reduction in price cannot be considered in assessing price erosion damages. Additionally, if after December 1, 2019, Genentech would have lowered its price in response to sales of biosimilar trastuzumab by licensed third-party competitors, that reduction in price also cannot be considered in assessing price erosion damages.

A. Genentech's Position

Genentech's neutral instruction comes from the AIPLA Model.

Amgen inserts incomplete facts regarding Mylan and improperly suggests it could sell Kanjinti during the damages period without infringing the Dosing Patents (which Genentech contests). Amgen's instruction improperly argues a hypothetical fact about the market after Mylan's launch.

B. Amgen's Position

If the jury finds that Amgen would have made sales of Kanjinti during the damages period without infringing the Dosing Patents, the jury must consider those sales in determining the extent of any price erosion. Mylan's biosimilar launch changed the dynamic of the trastuzumab market during the damages period, and also must be accounted for in determining the extent of any price erosion.

XXIX. Proposed Instruction 7.21: Damages – Doubts Resolved Against Infringer

GENENTECH'S PROPOSAL: Any doubts that you may have on the issue of damages due to Amgen's failure to keep proper records should be decided in favor of Genentech. Any confusion or difficulties caused by Amgen's records also should be held against Amgen, not Genentech.

A. Genentech's Position

If irrelevant, Genentech will withdraw; damages discovery is ongoing.

B. Amgen's Position

The quality or completeness of Amgen's financial record keeping is not an issue in this case.

XXX. Proposed Instruction 8: Willful Infringement

A. Disputed Proposal 1

[GENENTECH'S PROPOSAL: If you have decided that Amgen has infringed a valid claim of Genentech's patents, then you must go on and address the additional issue of whether or not this infringement was willful. In this case, Genentech alleges both that Amgen infringed the Asserted Patent Claims and, further, that Amgen infringed willfully. Amgen denies that its conduct was willful.]

[AMGEN'S PROPOSAL: In this case, Genentech alleges both that Amgen infringed and, further, that Amgen infringed willfully the Asserted Patent Claims. Amgen contends that its conduct was not willful because it had a reasonable belief that the Patents-in-Suit are invalid, not infringed, and/or unenforceable. Amgen additionally contends that its conduct was not willful in part because it relied on opinion of counsel that the Asserted Claims of the Kao Manufacturing Patent were neither valid nor infringed, and on opinion of counsel that the Asserted Claims of the Dosing Patents were invalid.

For any Asserted Patent Claim that is infringed, not invalid, and not unenforceable you must go on and address the additional issue of whether or not this infringement was willful.]

1. Genentech's Position

Genentech's proposal is modeled on *Orexo.*

Amgen's unduly emphasizes its position, which risks jury confusion. *See also* §**Error! Reference source not found.**.

2. Amgen's Position

Amgen's statement of its position states succinctly its response to Genentech's allegation of willful infringement. Proposal on unenforceability withdrawn.

B. Disputed Proposal 2

To show that Amgen's infringement was willful, Genentech must prove by a preponderance of the evidence that Amgen knew of a Patent-in-Suit and intentionally infringed at least one Asserted Patent Claim. However, you may not find that Amgen's infringement was willful merely because Amgen knew about a Patent-in-Suit and infringed it, without more. Instead, willful infringement requires Amgen to have acted despite a risk of infringement of a valid patent claim that was either known or so obvious that it should have been known to Amgen. AMGEN'S PROPOSAL: For example, in deciding whether or not Amgen knew it was infringing a patent it knew to be valid, you may consider whether Amgen's behavior was malicious, wanton, deliberate, consciously wrongful, flagrant, or in bad faith.

1. Genentech's Position

"Under [*Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1934 (2016)], … 'willfulness' requires a jury to find no more than deliberate or intentional infringement." *Eko Brands, LLC v. Adrian Rivera Maynez Enterprises, Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020) ("egregious" instruction erroneous). Including "examples" is unnecessary and overstates the standard.

2. Amgen's Position

Amgen's proposal is modeled on the F.C.B.A.'s willfulness instruction and this Court's willfulness instruction in *F'Real Foods*, modified for the Federal Circuit's guidance in *Eko Brands v. Adrian Rivera Maynez Enterprises*, No. 2018-2215, 2020 WL 130439, at *2 (Fed. Cir. Jan. 13, 2020).

C. Disputed Proposal 3

GENENTECH'S PROPOSAL: Whether or not Amgen intentionally copied an invention of Genentech that is covered by the Patents-in-Suit

1. Genentech's Position

Consideration of intentional copying is appropriate. *See, e.g., Polara Engineering Inc. v. Campbell Co.*, 894 F.3d 1339, 1353-54 (Fed. Cir. 2018). It is relevant because Amgen had the choice not to seek approval for infringing methods. The BPCIA did not require Amgen to copy the patents-in-suit.

2. Amgen's Position

Copying should not be included as a relevant factor for willful infringement because this case is brought under the BPCIA. Congress passed the BPCIA to facilitate expedited FDA approval of biosimilar products that are highly similar to the reference product, and to create a pathway to any patent litigation arising from those biosimilar products. Given the congressional intent to speed the approval and commercial availability of biosimilar products, including copying as a factor

for willfulness would be unfairly prejudicial to Amgen and would risk confusing the jury as to Amgen's compliance with the terms of the BPCIA.

D. Disputed Proposal 4

GENENTECH'S PROPOSAL: To the extent that you consider Amgen's reliance on an opinion of its outside counsel, you must evaluate whether the opinion was of a quality that reliance on its conclusions was reasonable. Factors you may consider when determining whether Amgen reasonably relied on the legal opinion include the timing of the opinion, the nature of the advice, the thoroughness and competence of the opinion, and its objectivity.

1. Genentech's Position

Genentech's proposal correctly identifies relevant factors for the jury to assess the weight of the opinion. *See, e.g.*, *SRI Int'l, Inc. v. Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1465 (Fed. Cir. 1997); *Aspex Eyewear Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1313 (Fed. Cir. 2010). It also clarifies that Amgen is relying on ***outside*** counsel's opinion, so that potential in-house counsel testimony will not be confusing.

2. Amgen's Position

Genentech's proposal places undue and prejudicial emphasis on Amgen's reliance on opinion of counsel.

XXXI. Preliminary Instructions

A. Disputed Instruction 1

GENENTECH'S PROPOSAL: Genentech alleges that Amgen infringes the Patents-in-Suit because of its filing of an Biologics License Application ("BLA") for a trastuzumab product that is a biosimilar of Herceptin, and by its importing, manufacturing, marketing, selling, or offering to sell that trastuzumab product.]

AMGEN'S PROPOSAL: Genentech alleges that Amgen infringes the Patents-in-Suit by its importing, manufacturing, marketing, selling, or offering to sell that trastuzumab product.

1. Genentech's Position

See §VII.A.

2. Amgen's Position

See Section IV.B.

B. Disputed Instruction 2

GENENTECH'S PROPOSAL: No instruction regarding derivation or inventorship is proper as those defenses should be stricken. See D.I. 445. To the extent any instruction is given, Genentech proposes: "Amgen also contends that the Asserted Claims of the Dosing Patents fail to name the correct inventors and are invalid because the claimed inventions were derived from another."

AMGEN'S PROPOSAL: Amgen also contends that the Asserted Claims of the Dosing Patents, if they represent any invention at all, are invalid for failing to name the correct inventors and because the claimed inventions were derived from Dr. Brian Leyland-Jones.

1. Genentech's Position

See D.I. 445.

2. Amgen's Position

See D.I. 456.

Respectfully submitted,

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